K031803
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JUL 1 2003

510(k) Summary

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Karla Ham Sr. Regulatory Affairs Associate
TRADE NAME:	DePuy Ceramic Femoral Heads
COMMON NAME:	Ceramic Femoral Ball Prosthesis
CLASSIFICATION:	888.3353: Hip joint femoral metal/ceramic/polymer, semi-constrained cemented or nonporous, uncemented prosthesis; **Class II**
DEVICE PRODUCT CODE:	87 LZO
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Femoral Heads, K011533

DEVICE DESCRIPTION AND INTENDED USE:
The DePuy Ceramic Femoral Heads are composed of an alumina composite material and are available in head diameters of 32mm and 36mm sizes with various offset options. The internal bore of the ceramic femoral head, which is designed to interlock with the external taper on the femoral hip stem, is available in two variations (11/13 SROM and 12/14 Articul/eze taper options).

The ceramic heads are designed to mate with a corresponding DePuy femoral hip stem and provide the femoral articular surface of a total hip replacement.

INDICATIONS FOR USE:
The DePuy Ceramic Femoral Heads are indicated for use as the femoral head component in total hip arthroplasty procedures. Total hip arthroplasty is intended to provide increased patient mobility and to reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

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BASIS OF SUBSTANTIAL EQUIVALENCE:

DePuy considers the Ceramic Femoral Heads to be substantially equivalent to the DePuy Femoral Heads submitted in K011533 based on similarities in design, same material composition, same sterilization and packaging methods, same intended use/indications for use, and similar labels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2003

Ms. Karla A. Ham
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthpaedic Drive
Warsaw, Indiana 46581-0988

Re: K031803
Trade/Device Name: DePuy Ceramic Femoral Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: June 10, 2003
Received: June 11, 2003

Dear Ms. Ham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031803

Device Name: **DePuy Ceramic Femoral Heads**

Indications for Use:

The DePuy Ceramic Femoral Heads are indicated for use as the femoral head component in total hip arthroplasty procedures.
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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5. Certain cases of ankylosis.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031803

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CFR 801.109)